



“FDA Adverse Event Reporting System (FAERS) Public Dashboard”

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DISCLAIMER



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LEARNING OBJECTIVES



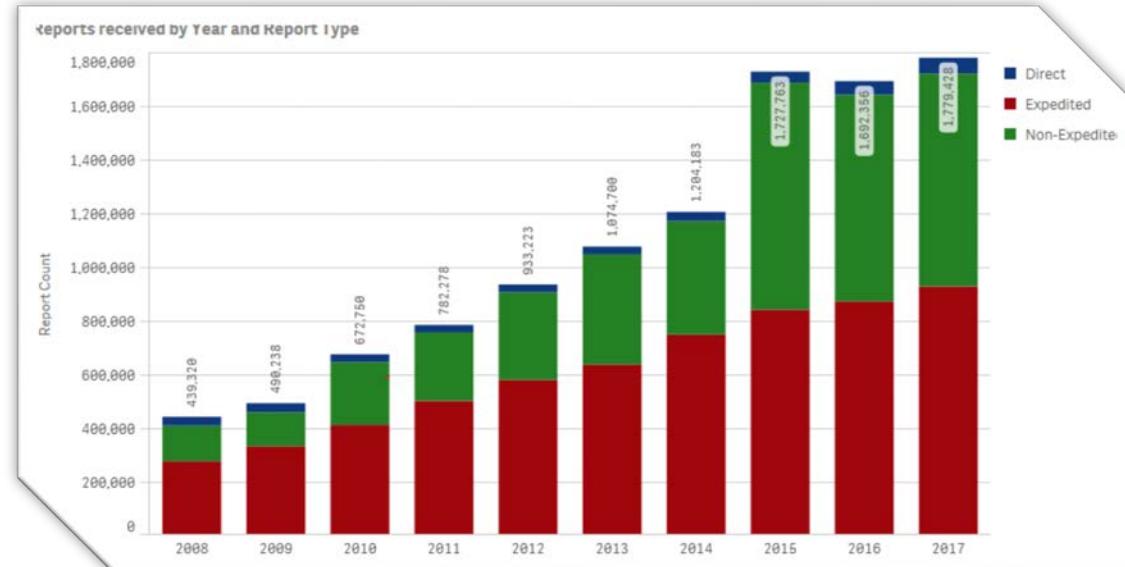
- Describe the FAERS public database
- Demonstrate how to use the FAERS public dashboard to view adverse event reporting metrics
- Illustrate use of FAERS public dashboard to view adverse event information on a specific product

BACKGROUND



The FDA Adverse Events Reporting System (FAERS) is a database that contains spontaneous adverse event reports that are submitted to FDA from the product manufacturer or directly from the consumer, healthcare professional, or other reporter. The database supports the FDA's post marketing safety surveillance program for drug and therapeutic biologic products.

The database consists of more than fourteen (14) million reports since 1969 to August 2017. Each year, FDA receives over one (1) million adverse events and medication error reports associated with the use of drug or biologic products. Existence of a report does not establish causation.



OBJECTIVE



FDA provides information to the public in an accessible and transparent manner. This new FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports and making adverse event data more accessible and transparent.

FAERS data outlets for public:



Open FDA

JSON File(s)

The screenshot shows the QDE page with a large blue banner at the top stating "Text/ASCII Files and XML File(s)". Below the banner, there are three download links: "JSON File", "XML File", and "CSV File". The page also includes a brief description of what QDE is and how to use it.

FAERS Quarterly Data Extracts (QDE)



Easy Interactive Access

FAERS Public Dashboard

The FAERS Public Dashboard is an interactive application, which enables the user to search for information related to adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

KEY POINTS TO CONSIDER



Data Quality

- There are many instances of duplicative reports and some reports do not contain all the necessary information.

Existence of a report does not establish causation

- There is no certainty that a suspected drug caused the adverse events.
- Adverse events may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.
- The information in these reports reflects only the reporter's observations and opinions.

Information in reports has not been verified

- Submission of a report does not mean that the information included in it has been medically confirmed.

KEY POINTS TO CONSIDER



- ❑ **Rates of occurrence cannot be established with reports**
 - The number of adverse events should not be used to determine the likelihood of a side effect occurring.
 - Factors such as the time a product has been marketed and publicity can influence reporting.
- ❑ **Patients should talk to their doctor** before stopping or changing how they take their medications
- ❑ **Patient Outcomes received in FAERS**
 - A reported serious outcomes does not necessarily mean that the suspect product(s) named in the report was the cause of these outcomes.



FAERS data by themselves are not an indicator that the drug is causing the reported adverse events.

SPONTANEOUS REPORTS

- A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
- Describes a suspected adverse event(s)
- Passive and voluntary reports

FACTORS AFFECTING REPORTING

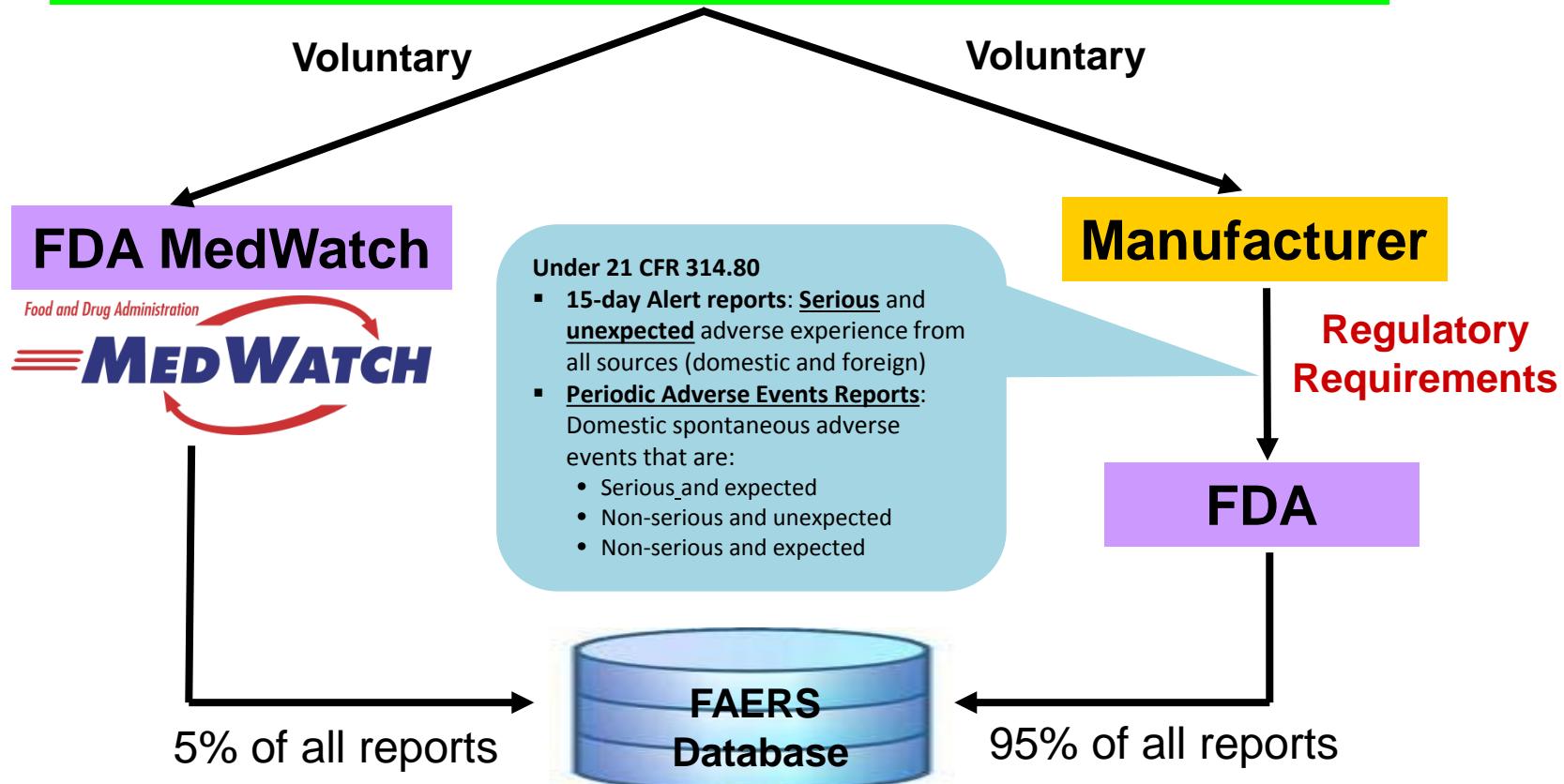


- Media attention
- Litigation (class action lawsuits)
- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter (OTC) product status
- Reporting regulations

HOW POSTMARKETING REPORTS GET TO FDA



Patients, consumer, and healthcare professionals



FAERS STRENGTHS

- Includes all U.S. marketed products
- Includes all uses
- Includes broad patient populations:
 - elderly, children, pregnant women, comorbidities
- Especially good for events with a rare background rate
- Useful for events that occur shortly after exposure
- Detection of events not seen in clinical trials (“signal generation”)
- Identification of reporting trends, possible risk factors, at risk populations, and other clinically significant emerging safety concerns

FAERS IS LESS USEFUL FOR

- Events with high background rates
- Worsening of pre-existing disease
- Issue that goes beyond data captured from the MedWatch Form or electronic reporting
- Comparative incidence rates
- Comparing drugs in the same class
- Adverse events that could also be manifestations of the disease for which the drug is indicated



FAERS PUBLIC DASHBOARD

LAUNCH FAERS PUBLIC DASHBOARD

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm>

The screenshot shows the FDA Adverse Events Reporting System (FAERS) Public Dashboard. The page has a dark blue header with the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, etc. Below the header, there's a breadcrumb trail: Home > Drugs > Guidance, Compliance & Regulatory Information > Surveillance > FDA Adverse Events Reporting System (FAERS). The main content area is titled "FDA Adverse Events Reporting System (FAERS) Public Dashboard". It features a summary of the tool's purpose, limitations, and key findings. A sidebar on the left lists links such as "FDA Adverse Event Reporting System (FAERS) Latest Quarterly Data Files", "FDA Adverse Events Reporting System (FAERS) Public Dashboard", "Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)", and "FDA Adverse Events Reporting System (FAERS) Electronic Submissions". At the bottom, there's a call-to-action button: "Launch the FDA Adverse Events Reporting System (FAERS) Public Dashboard".

DISCLAIMER

FDA

Disclaimer

Each year, the FDA receives over one million adverse event and medication error reports associated with the use of drug or biologic products. The FDA uses these reports to monitor the safety of drug and biological products. The FDA Adverse Event Reporting System (FAERS) database houses reports submitted to the FDA by drug manufacturers (who are required to submit these reports to FDA) and others such as health care professionals and consumers. Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use. Because of this, FAERS data comprise only one part of the FDA's important post-market surveillance data and the information on this website does not confirm a causal relationship between the drug product and the reported adverse event(s).

- Consumers should not stop or change medication without first consulting with a health care professional.
- The FAERS web search feature is limited to adverse event reports between 1969 and the most recent quarter for which data are available.
- Data submitted to the FAERS system will be made available through the new querying tool on a quarterly basis.
- FAERS data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with drug products.
- Confirming whether a drug product actually caused a specific event can be difficult based solely on information provided in a given report.
- FAERS data do not represent all known safety information for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.

Importantly, safety reports submitted to FDA do not necessarily reflect a conclusion by FDA that the information in the reports constitutes an admission that the drug caused or contributed to an adverse event. Individual FAERS reports for a given product can be requested by submitting a Freedom of Information Act (FOIA) request at:

<http://www.fda.gov/regulatoryinformation/foi/howtomakeafoiarequest/default.htm>

Accept

Do Not Accept

Click on “Accept” to accept
disclaimer and view
information on the
dashboard

QUESTION 1

Select all the key points to consider while viewing the contents of the dashboard

- a. Quality of adverse event data
- b. Existence of a report does not establish causation
- c. Information in reports has not been verified
- d. Rates of occurrence cannot be established with reports
- e. Patients should talk to their doctor before stopping or changing their medication
- f. All of the above

QUESTION 2

Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

- a. Yes
- b. No

QUESTION 2

Dr. Doe a private physician views adverse event data on a product. Looking at the volume of the data set for that product he concludes that the product is risky to prescribe.

Did Dr. Doe make an informed decision?

- a. Yes
- b. No

- Existence of a report does not establish causation
- Rates of occurrence cannot be established with reports

KEY PARTS OF DASHBOARD

Filter panel



Navigation panel



Count panel



KEY PARTS OF DASHBOARD



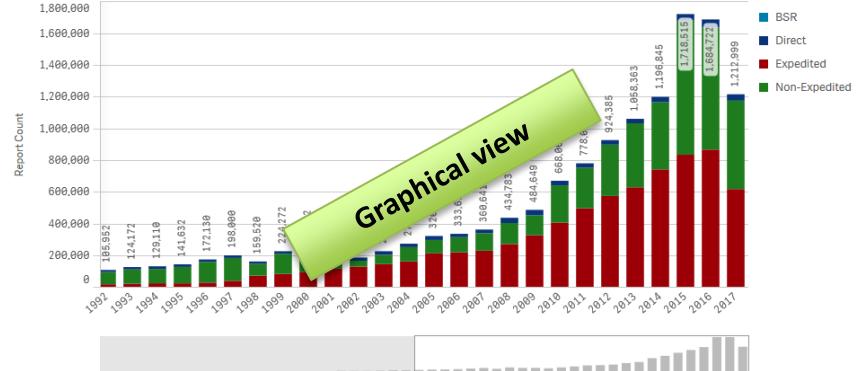
Data panel

Reports received by Year and Report Type

| | Year ▾ | Category ▾ | Total Reports | Expedited | Non-Expedited | Direct | BSR |
|----------------------|-------------------|------------------|----------------|---------------|---------------|----------------|------------|
| Total Reports | 14,160,191 | 7,437,939 | 615,558 | 54,771 | 6,852 | 739,781 | 873 |
| 2017 | 1,212,999 | 615,558 | - | - | - | 49,383 | - |
| 2016 | 1,684,722 | 864,309 | - | - | - | 50,879 | - |
| 2015 | 1,718,515 | 831,177 | - | - | - | 41,539 | - |
| 2014 | 1,196,845 | 423,150 | - | - | - | 34,114 | - |
| 2013 | 1,058,363 | 403,368 | - | - | - | 28,303 | - |
| 2012 | 924,385 | 323,059 | - | - | - | 28,866 | - |
| 2011 | 778,728 | 255,058 | - | - | - | 27,995 | - |
| 2010 | 664,566 | 404,586 | - | - | - | 28,902 | - |
| 2009 | 484,414 | 324,421 | - | - | - | 34,890 | - |
| 2008 | 434,783 | 269,298 | - | - | - | 32,826 | - |
| 2007 | 360,641 | 227,294 | - | - | - | 22,958 | - |
| 2006 | 333,629 | 217,213 | - | - | - | 20,891 | - |
| 2005 | 320,016 | 210,363 | - | - | - | 25,175 | 6 |
| 2004 | 271,418 | 160,008 | - | - | - | 21,572 | 5 |
| 2003 | 222,444 | 140,750 | - | - | - | 22,070 | 14 |

Tabular view

Reports received by Year and Report Type



Graphical view

Page help panel

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

- Direct Reports are voluntarily submitted directly to FDA through the MedWatch program by consumers and healthcare professionals.
- Mandatory Reports are submitted by manufacturers and are categorized as:
 - i. Expedited reports that contain at least one adverse event that is not currently described in the product labeling and for which the patient outcome is serious, or
 - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.

Describes the details of data displayed on the page

MAIN DASHBOARD PAGE



Main Dashboard Page Selected filter criteria

No selections applied

FDA Adverse Events Reporting System (AERS) Public Dashboard

Home Q Search for Products

Total Reports **14,160,191**

Serious Reports (excluding death) **8,072,400**

Death Reports **1,420,885**

Provides an option to search adverse event by product

Displays counts of all death reports

View Disclaimer

Report an adverse event via a web portal

Frequently Asked Questions

U.S. FOOD & DRUG ADMINISTRATION

Reports received by Year and Report Type

Year ▾ Category ▾

| | Total Reports | Expedited | Non-Expedited | Direct | BSR |
|---------------|---------------|-----------|---------------|---------|-----|
| Total Reports | 14,160,191 | 7,437,939 | 5,981,598 | 739,781 | 873 |
| 2017 | 1,212,999 | 615,558 | 557,058 | 40,383 | - |
| 2016 | 1,684,722 | 864,309 | 769,534 | 50,879 | - |
| 2015 | 1,718,515 | 831,924 | 15,052 | 41,539 | - |
| 2014 | 1,196,845 | 739,581 | 150 | 34,114 | - |
| 2013 | 1,058,363 | 626,602 | 103,368 | 28,303 | - |
| 2012 | 924,385 | 520,300 | 323,059 | 28,866 | - |
| 2011 | 778,014 | 420,000 | 255,058 | 27,995 | - |
| 2010 | 668,066 | 445,586 | 234,578 | 28,902 | - |
| 2009 | 484,000 | 324,421 | 126,138 | 34,090 | - |
| 2008 | 434,000 | 269,298 | 132,659 | 32,826 | - |
| 2007 | 360,641 | 227,294 | 110,389 | 22,958 | - |
| 2006 | 333,629 | 217,213 | 95,525 | 20,891 | - |
| 2005 | 320,016 | 210,363 | 84,472 | 25,175 | 6 |
| 2004 | 271,418 | 160,008 | 89,833 | 21,572 | 5 |
| 2003 | 229,444 | 140,750 | 60,601 | 20,070 | 14 |

Tabular view

Reports received by Year and Report Type

Report Count

Graphical view

Data as of August 31, 2017

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

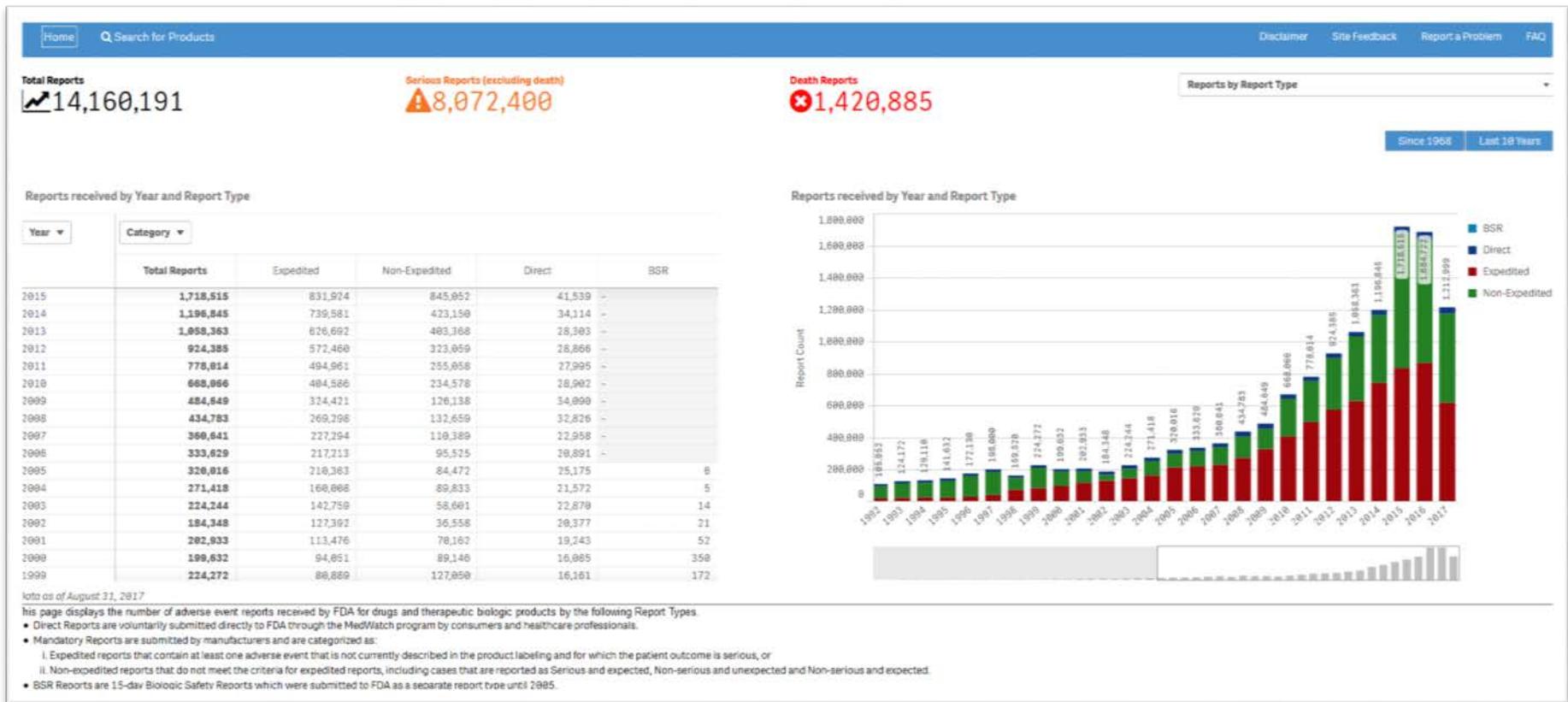
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 - ii. Non-expedited reports that do not meet the criteria for expedited reports, including cases that are reported as Serious and expected, Non-serious and unexpected and Non-serious and expected.
- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Describes the details of data displayed on the page

MAIN DASHBOARD

REPORTS BY REPORT TYPE

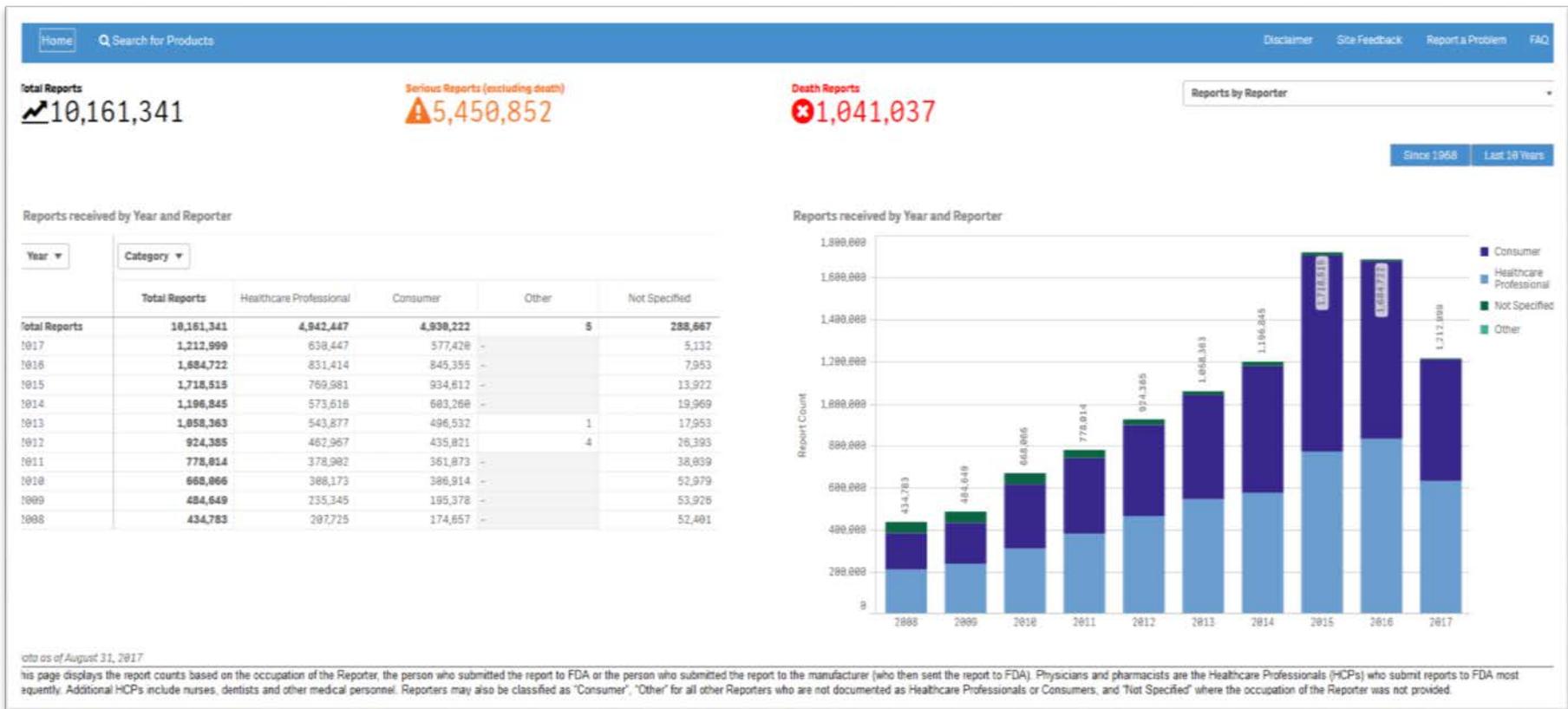
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by report type



MAIN DASHBOARD

REPORTS BY REPORTER

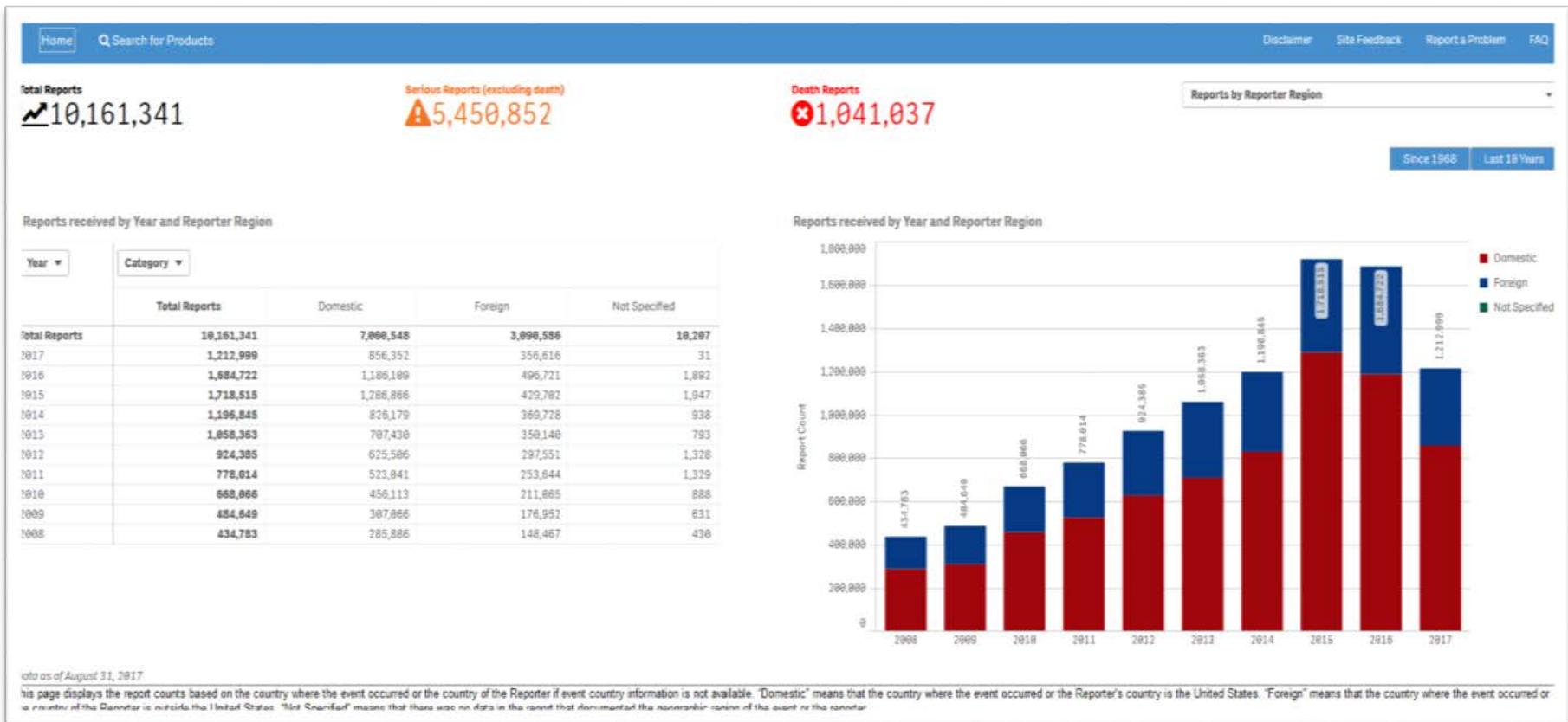
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by type of reporter



MAIN DASHBOARD

REPORTS BY REPORTER REGION

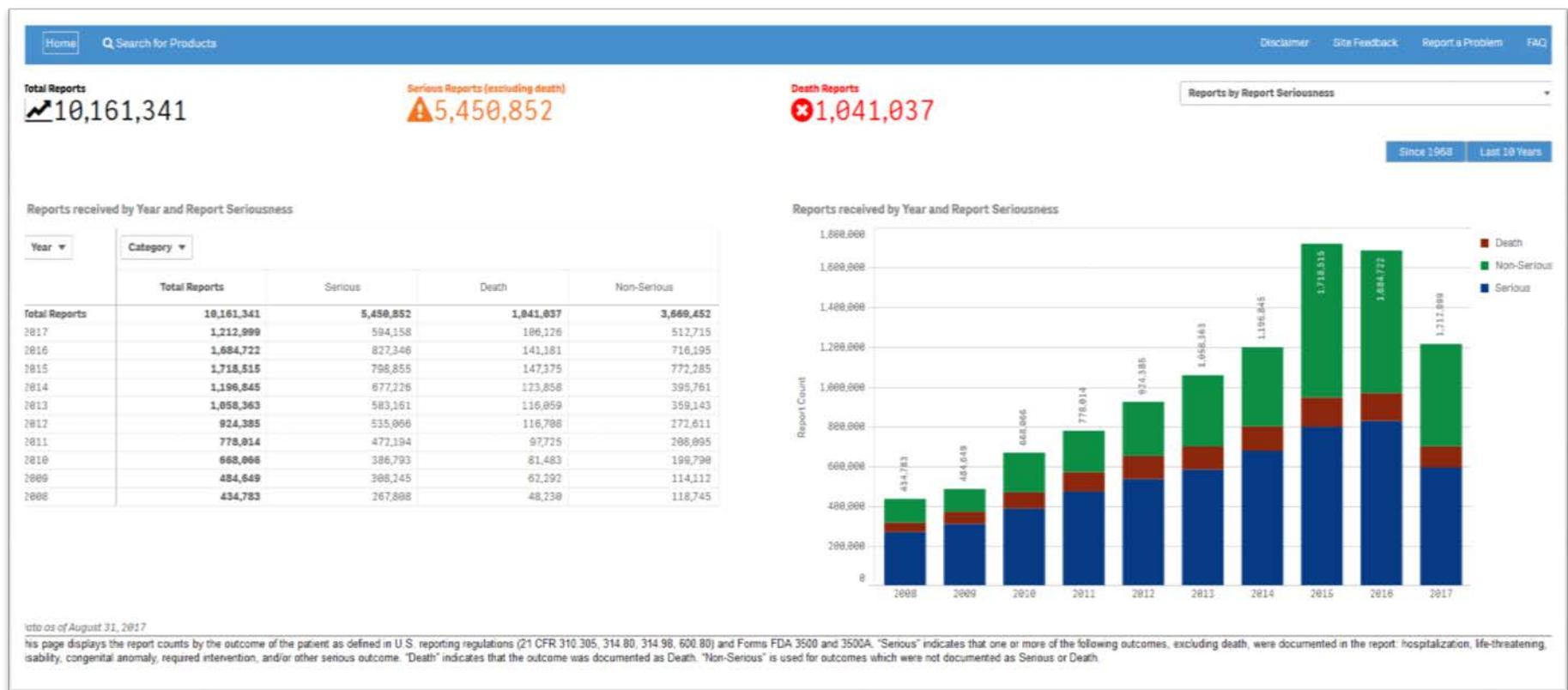
Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic based on the country where the event occurred.



MAIN DASHBOARD

REPORTS BY REPORT SERIOUSNESS

Displays the number of adverse event reports received by FDA for drugs and therapeutic biologic by outcome of the patient as defined in regulations (21CFR 310.305, 314.80, 314.98, 600.80) and FDA MedWatch forms (3500 and 3500B)



QUESTION 3

The report counts on the main dashboard page are the counts of reports that include initials and follow-ups

- a. True
- b. False

QUESTION 4

The main dashboard page displays report counts on which of the following criteria

- a. Report Type
- b. Reporter
- c. Reporter Region
- d. Report Seriousness
- e. All of the above



SEARCH FOR PRODUCTS

SEARCH FOR PRODUCTS



Search for products

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Total Reports **14,160,191**

Serious Reports (excluding death) **8,072,400**

Death Reports **1,420,885**

Reports by Report Type Since 1968 Last 10 Years

Reports received by Year and Report Type

| Year | Category | Total Reports | Expedited | Non-Expedited | Direct | BSR |
|---------------|----------|---------------|-----------|---------------|---------|-----|
| Total Reports | | 14,160,191 | 7,437,939 | 5,981,598 | 739,781 | 873 |
| 2017 | | 1,212,999 | 615,558 | 557,058 | 48,383 | - |
| 2016 | | 1,684,722 | 864,389 | 769,534 | 58,879 | - |
| 2015 | | 1,718,515 | 831,924 | 845,852 | 41,539 | - |
| 2014 | | 1,196,845 | 739,581 | 423,158 | 34,114 | - |
| 2013 | | 1,058,363 | 626,692 | 483,368 | 28,303 | - |
| 2012 | | 924,385 | 572,466 | 323,059 | 28,866 | - |
| 2011 | | 778,014 | 494,961 | 255,058 | 27,995 | - |
| 2010 | | 668,066 | 484,586 | 234,578 | 28,902 | - |
| 2009 | | 484,649 | 324,421 | 176,138 | 34,098 | - |
| 2008 | | 434,783 | 269,298 | 132,659 | 32,826 | - |
| 2007 | | 366,641 | 227,294 | 118,389 | 22,958 | - |
| 2006 | | 333,629 | 217,213 | 95,525 | 28,891 | - |
| 2005 | | 320,016 | 210,363 | 84,472 | 25,175 | 6 |
| 2004 | | 271,418 | 160,088 | 89,833 | 21,572 | 5 |
| 2003 | | 224,244 | 142,759 | 58,601 | 22,878 | 14 |
| 2002 | | 184,348 | 127,392 | 36,558 | 28,377 | 21 |

Data as of August 31, 2017

This page displays the number of adverse event reports received by FDA for drugs and therapeutic biologic products by the following Report Types.

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- BSR Reports are 15-day Biologic Safety Reports which were submitted to FDA as a separate report type until 2005.

Reports received by Year and Report Type

| Year | BSR | Direct | Expedited | Non-Expedited | Total |
|------|-----|--------|-----------|---------------|-----------|
| 1992 | 0 | 0 | 0 | 8 | 8 |
| 1993 | 0 | 0 | 0 | 124,172 | 124,172 |
| 1994 | 0 | 0 | 0 | 124,118 | 124,118 |
| 1995 | 0 | 0 | 0 | 141,632 | 141,632 |
| 1996 | 0 | 0 | 0 | 172,130 | 172,130 |
| 1997 | 0 | 0 | 0 | 198,080 | 198,080 |
| 1998 | 0 | 0 | 0 | 198,420 | 198,420 |
| 1999 | 0 | 0 | 0 | 224,472 | 224,472 |
| 2000 | 0 | 0 | 0 | 199,632 | 199,632 |
| 2001 | 0 | 0 | 0 | 202,893 | 202,893 |
| 2002 | 0 | 0 | 0 | 232,344 | 232,344 |
| 2003 | 0 | 0 | 0 | 271,418 | 271,418 |
| 2004 | 0 | 0 | 0 | 310,816 | 310,816 |
| 2005 | 0 | 0 | 0 | 333,629 | 333,629 |
| 2006 | 0 | 0 | 0 | 366,641 | 366,641 |
| 2007 | 0 | 0 | 0 | 434,783 | 434,783 |
| 2008 | 0 | 0 | 0 | 484,649 | 484,649 |
| 2009 | 0 | 0 | 0 | 561,086 | 561,086 |
| 2010 | 0 | 0 | 0 | 668,066 | 668,066 |
| 2011 | 0 | 0 | 0 | 778,014 | 778,014 |
| 2012 | 0 | 0 | 0 | 924,385 | 924,385 |
| 2013 | 0 | 0 | 0 | 1,086,363 | 1,086,363 |
| 2014 | 0 | 0 | 0 | 1,196,846 | 1,196,846 |
| 2015 | 0 | 0 | 0 | 1,212,999 | 1,212,999 |
| 2016 | 0 | 0 | 0 | 1,684,722 | 1,684,722 |
| 2017 | 0 | 0 | 0 | 1,718,515 | 1,718,515 |

SEARCH FOR PRODUCTS

A screenshot of the FDA Adverse Events Reporting System (FAERS) Public Dashboard. At the top, there is a dark header bar with the text "No selections applied". Below it is a light blue navigation bar containing the text "FDA Adverse Events Reporting System (FAERS) Public Dashboard", the "FDA U.S. FOOD & DRUG ADMINISTRATION" logo, and links for "Home", "Search for Products", "Disclaimer", "Site Feedback", "Report a Problem", and "FAQ". The main content area has a white background and features a search bar labeled "Search for a Product" with a magnifying glass icon. A large green callout bubble with a black border and a yellow arrow points from the bottom right towards the search bar. Inside the callout bubble, the text reads: "Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability".

No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Search for Products Disclaimer Site Feedback Report a Problem FAQ

Search for a Product

Search for a product (brand name) or active ingredient (generic name). This field provides a smart search capability

SEARCH FOR PRODUCTS



No selections applied

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Disclaimer Site Feedback Report a Problem FAQ

Field to search for both brand name and generic name products. Typing three letters provides all match texts highlighted in yellow.

Select “Amlodipine Besylate”

P (in green color) – Brand Name of the product

G (in orange color) – Generic Name of the product

Search for a Product

- ami
- Amlodipine
- Amlodipine And Atorvastatin
- Amlodipine And Olmesartan Medoxomil
- Amlodipine And Valsartan
- Amlodipine Besylate**
- Amlodipine Besylate And Atorvastatin Calcium
- Amlodipine Besylate And Benazepril Hydrochloride
- Amlodipine Besylate And Valsartan
- Amlodipine Besylate/Atorvastatin Calcium

QUESTIONS 5

Rebecca is a researcher at a university and is currently researching on a recently approved drug with NDA number 209310 (i.e. SINUVA – brand name, MOMETASONE FUROATE – generic name). She is exploring FAERS public dashboard to find information on the product of interest.

Select the applicable options for her to perform a search for product details?

- a. By NDA number
- b. By Brand Name
- c. By Generic Name
- d. By Brand Name or Generic Name
- e. None of the above

SEARCH PRODUCT RESULT



Filter applied for the selected product

Total number of latest version of the reports listed

Selected product displayed

List of reports available

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases **47,204**

serious Cases [including deaths] **41,047**

Death-Cases **6,608**

Case Count by Received Year

| Category | Q. | Number of Cases | Percentage |
|---------------|----|-----------------|----------------|
| 2017 | | 3,352 | 7.18% |
| 2016 | | 4,974 | 8.53% |
| 2015 | | 3,771 | 7.88% |
| 2014 | | 3,333 | 7.86% |
| 2013 | | 3,496 | 7.41% |
| 2012 | | 2,553 | 5.41% |
| 2011 | | 2,342 | 4.96% |
| 2010 | | 2,318 | 4.91% |
| 2009 | | 1,323 | 2.88% |
| 2008 | | 961 | 2.04% |
| 2007 | | 1,821 | 2.18% |
| 2006 | | 938 | 1.97% |
| 2005 | | 892 | 1.89% |
| Totals | | 47,204 | 100.00% |

Case Count by Received Year

Cases by Received Year

Cases by Reaction

Cases by Age Group

Cases by Sex

Cases by Reporter Type

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by 'Received Year'. 'Received Year' is the year the case was received by the FDA.

DEMOGRAPHICS



Filters applied for years

Drag the mouse to select years or by individual clicks

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases 3,352

Serious Cases (including deaths) 2,761

Death Cases 619

Case Count by Received Year

| Category | Number of Cases | Percentage |
|---------------|-----------------|----------------|
| 2017 | 3,352 | 16.33% |
| 2016 | 4,074 | 19.85% |
| 2015 | 3,721 | 18.13% |
| 2014 | 3,333 | 16.24% |
| 2013 | 3,496 | 17.03% |
| 2012 | 2,553 | 12.44% |
| Totals | 20,529 | 100.00% |

Cases by Received Year

| Received Year | Number of Cases |
|---------------|-----------------|
| 2017 | 3,352 |
| 2016 | 4,074 |
| 2015 | 3,721 |
| 2014 | 3,333 |
| 2013 | 3,496 |
| 2012 | 2,553 |
| 2011 | 2,342 |
| 2010 | 2,318 |
| 2009 | 1,323 |
| 2008 | 961 |
| 2007 | 1,021 |
| 2006 | 938 |
| 2005 | 892 |
| 2004 | 714 |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Received Year

Case Count by Received Year

| Category | Number of Cases | Percentage |
|----------|-----------------|------------|
| 2017 | 3,352 | 16.33% |
| 2016 | 4,074 | 19.85% |
| 2015 | 3,721 | 18.13% |
| 2014 | 3,333 | 16.24% |
| 2013 | 3,496 | 17.03% |
| 2012 | 2,553 | 12.44% |
| Totals | 20,529 | 100.00% |

Data as of August 2017. This page displays the number of cases identified for the product of interest by "Received Year". "Received Year" is the year the case was received by the FDA.

Case by years - tabular view

Case by years - graphical view

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reactions

FDA Adverse Events Reporting System (FAERS) Public Dashboard

U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Reaction

Case Count by Reaction

| Category | Number of Cases | Percentage |
|----------------------------|-----------------|----------------|
| Completed Suicide | 1,702 | 8.29% |
| Hypotension | 1,692 | 8.24% |
| Dizziness | 1,130 | 5.50% |
| Drug Hypersensitivity | 1,092 | 5.32% |
| Toxicity To Various Agents | 1,089 | 5.30% |
| Drug Interaction | 957 | 4.66% |
| Drug Ineffective | 917 | 4.47% |
| Headache | 894 | 4.35% |
| Dyspnoea | 884 | 4.31% |
| Overdose | 830 | 4.04% |
| Fatigue | 816 | 3.97% |
| Malaise | 761 | 3.71% |
| Acute Kidney Injury | 734 | 3.58% |
| Totals | 20,529 | 100.00% |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction". "Reaction" is the suspected side effect (also known as adverse event or adverse drug reaction) reported by the reporter and is based on the MedDRA dictionary Preferred Term (PT). A "Reaction" is a unique medical condition, sign, disease, diagnosis, therapeutic indication, investigation, surgical or medical procedure, etc. A case may contain more than one "Reaction".

Reactions listed in descending order

Scrollbar to view all reactions

| Reaction | Number of Cases |
|----------------------------|-----------------|
| Completed Suicide | 1,702 |
| Hypotension | 1,692 |
| Dizziness | 1,130 |
| Drug Hypersensitivity | 1,092 |
| Toxicity To Various Agents | 1,089 |
| Drug Interaction | 957 |
| Drug Ineffective | 917 |
| Headache | 894 |
| Dyspnoea | 884 |
| Overdose | 830 |
| Fatigue | 816 |
| Malaise | 761 |
| Acute Kidney Injury | 734 |
| Intentional Overdose | 734 |

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Age Group

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Search Term Amlodipine Besylate Received Year 6 of 59

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

FDA U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BEZYLATE



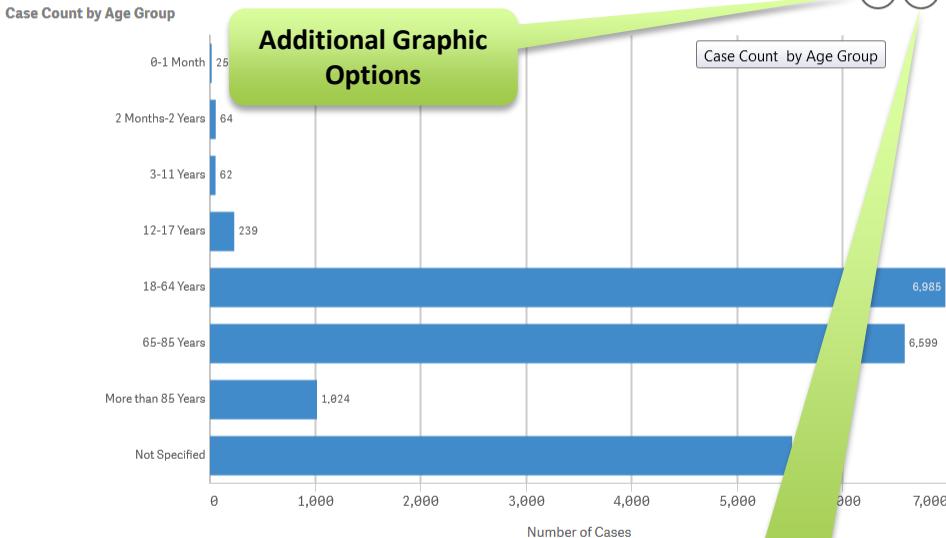
Total Cases
20,529

Serious Cases (including deaths)
16,459

Death Cases
3,146

Cases by Age Group

| Category | Number of Cases | Percentage |
|--------------------|-----------------|----------------|
| 0-1 Month | 25 | 0.12% |
| 2 Months-2 Years | 64 | 0.31% |
| 3-11 Years | 62 | 0.30% |
| 12-17 Years | 239 | 1.16% |
| 18-64 Years | 6,985 | 34.03% |
| 65-85 Years | 6,599 | 32.14% |
| More than 85 Years | 1,024 | 4.99% |
| Not Specified | 5,531 | 26.94% |
| Totals | 20,529 | 100.00% |



Additional Graphic Options

Click to expand the view

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by the reported age of the patient. "Not Specified" indicates the patient's age was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Sex

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

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AMLODIPINE BESYLATE



Total Cases
20,529

Serious Cases (including deaths)
16,459

Death Cases
3,146

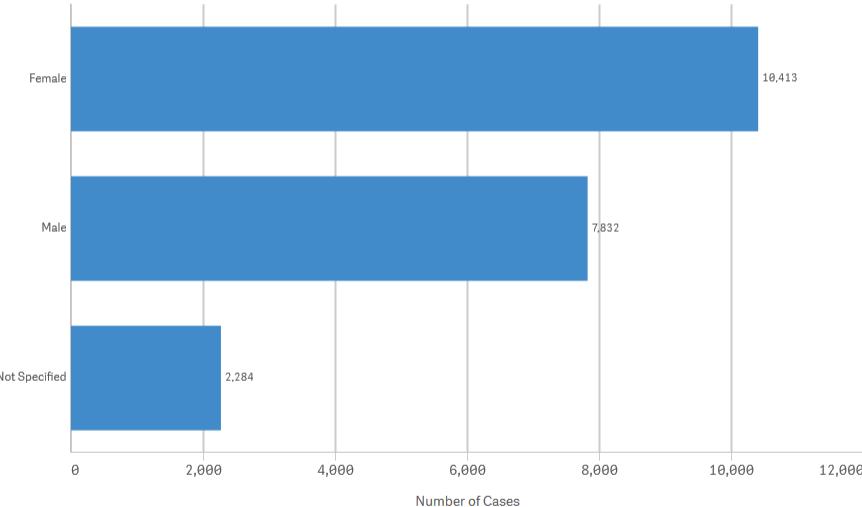
Cases by Sex



Case Count by Sex

| Category | Number of Cases | Percentage |
|---------------|-----------------|------------|
| Female | 10,413 | 50.72% |
| Male | 7,832 | 38.15% |
| Not Specified | 2,284 | 11.13% |
| Totals | 20,529 | 100.00% |

Case Count by Sex



Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by sex. "Not Specified" indicates the patient's sex was not reported.

DEMOGRAPHICS



Years filter applied from 2012 to 2017

Total number of cases for the 2012 to 2017

Cases by Reporter Type

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 20,529

Serious Cases (including deaths) 16,459

Death Cases 3,146

Cases by Reporter Type

| Category | Number of Cases | Percentage |
|-------------------------|-----------------|----------------|
| Healthcare Professional | 13,273 | 64.65% |
| Consumer | 6,816 | 33.20% |
| Not Specified | 440 | 2.14% |
| Totals | 20,529 | 100.00% |

Case Count by Reporter

| Reporter Type | Number of Cases |
|-------------------------|-----------------|
| Healthcare Professional | 13,273 |
| Consumer | 6,816 |
| Not Specified | 440 |

Data as of August 31, 2017

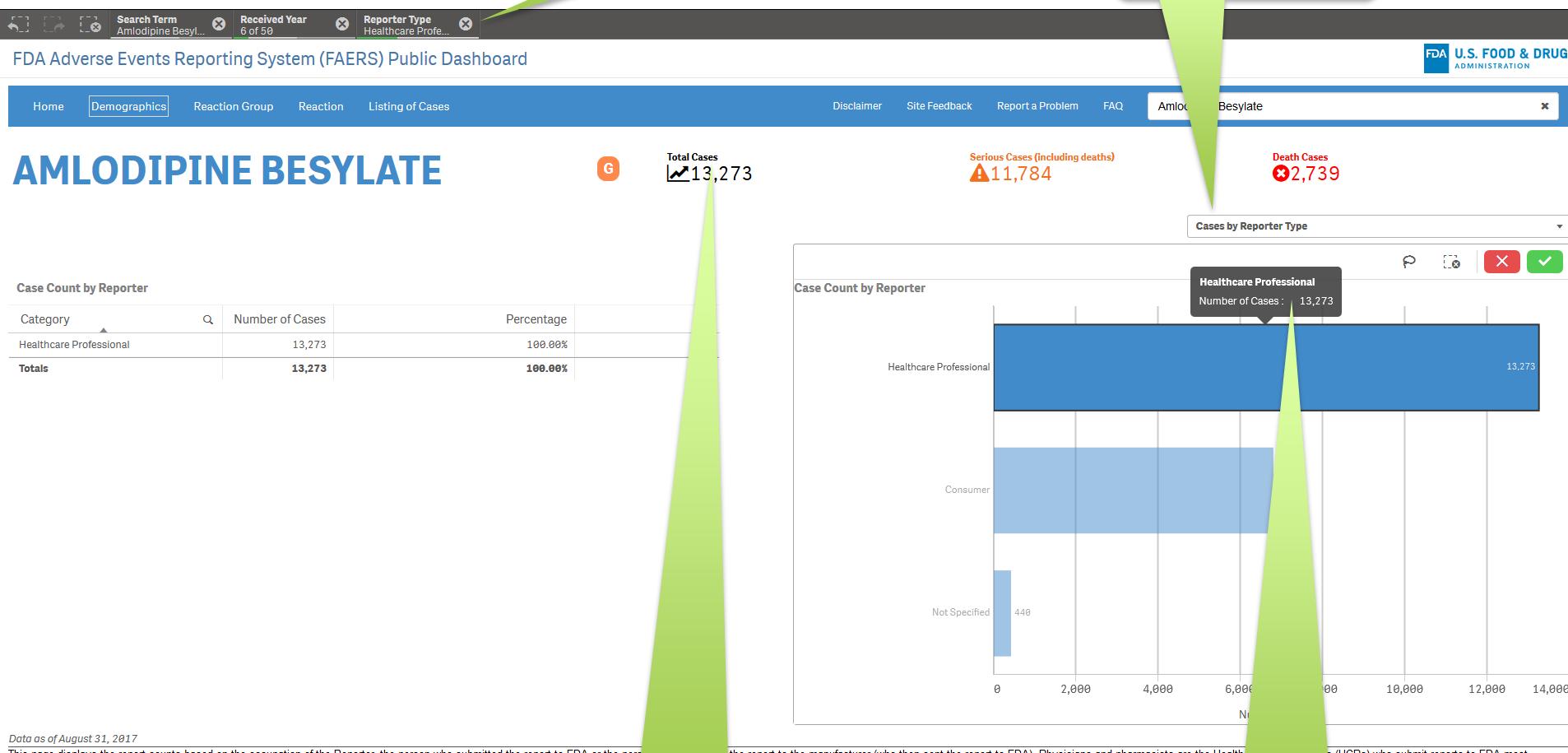
This page displays the report counts based on the occupation of the Reporter, the person who submitted the report to FDA or the person who submitted the report to the manufacturer (who then sent the report to FDA). Physicians and pharmacists are the Healthcare Professionals (HCPs) who submit reports to FDA most frequently. Additional HCPs include nurses, dentists and other medical personnel. Reporters may also be classified as "Consumer", "Other" for all other Reporters who are not documented as Healthcare Professionals or Consumers, and "Not Specified" where the occupation of the Reporter was not provided.

DEMOGRAPHICS



Reporter type filter
“Healthcare Professional” applied

Cases by Reporter Type



Total number of cases based on applied filter

Hover over to view information

QUESTIONS 6



Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for the reaction hypotension. How many steps does Rebecca need to get her results?

- a. 5
- b. 3
- c. 2
- d. 4

QUESTIONS 6

Rebecca is looking for the information about “Amlodipine Besylate” from 2012 to 2017 and reports from healthcare professional only. Then she decides to look for reaction related to hypotension. How many steps Rebecca need to perform to reach to her results?

- a. 5
- b. 3
- c. 2
- d. 4

Step 1: Select product (Amlodipine Besylate)

Step 2: Select Years (2012 to 2017)

Step 3: Select Reporter Type (healthcare professional)

Step 4: Click on reaction (hypotension)

QUESTIONS 7



Rebecca has applied the age groups 12-17 years and 18-64 in the previous exercise. Now she decides to remove the healthcare professional filter.

What is the best option to remove the healthcare professional filter?

- a. Deselect from "Cases by Reporter Type" page
- b. Unselect Reporter Type from filter section on top
- c. Resetting entire filters
- d. Start a new search

QUESTIONS 8



Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked a question to helpdesk about details of “Not Specified.”

What is the best answer helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgender
- c. Missing gender information
- d. Sex was not reported

QUESTIONS 8



Rebecca is confused with the information provided in “Case by Sex” as “Not Specified.” While examining the information she asked the helpdesk a question about details of “Not Specified.”

What is the best answer the helpdesk can provide?

- a. Sex is reported as unknown
- b. Transgenders
- c. Missing gender information
- d. Sex was not reported

“Not Specified” indicates the patient’s sex was not reported as these reports are voluntary.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Age Group

FDA Adverse Events Reporting System (FAERS) Public Dashboard

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AMLODIPINE BESYLATE

Total Cases **5,325**

Serious Cases (including deaths) **4,952**

Death Cases **1,554**

Cases by Age Group

Reaction Groups & Age Group

| Reaction Group | Select category | Number of Cases | 12-17 Years | 18-64 Years |
|--|-----------------|-----------------|-------------|-------------|
| Total Cases | | 5,325 | 228 | 5,097 |
| Psychiatric Disorders | | 1,895 | 78 | 1,817 |
| Injury, Poisoning And Procedural Complications | | 1,882 | 168 | 1,714 |
| Vascular Disorders | | 1,317 | 127 | 1,190 |
| General Disorders And Administration Site Conditions | | 1,249 | 74 | 1,175 |
| Nervous System Disorders | | 1,126 | 76 | 1,050 |
| Cardiac Disorders | | 1,001 | 88 | 913 |
| Respiratory, Thoracic And Mediastinal Disorders | | 823 | 39 | 784 |
| Investigations | | 800 | 75 | 725 |
| Gastrointestinal Disorders | | 772 | 55 | 717 |
| Metabolism And Nutrition Disorders | | 672 | 45 | 627 |
| Renal And Urinary Disorders | | 643 | 38 | 605 |
| Skin And Subcutaneous Tissue Disorders | | 565 | 23 | 542 |
| Musculoskeletal And Connective Tissue Disorders | | 428 | 12 | 408 |
| Infections And Infestations | | 285 | 27 | 258 |
| Immune System Disorders | | 261 | 5 | 256 |
| Hepatobiliary Disorders | | 186 | 5 | 181 |
| Eye Disorders | | 186 | 5 | 181 |
| Blood And Lymphatic System Disorders | | 180 | 13 | 167 |
| Surgical And Medical Procedures | | 98 | 8 | 90 |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

Reaction Groups & Age Group

| Reaction Group | 12-17 Years | 18-64 Years |
|--|-------------|-------------|
| Psychiatric Disorders | 1895 | 1882 |
| Injury, Poisoning And Procedural Complications | 1882 | 1882 |
| Vascular Disorders | 1317 | 1317 |
| General Disorders And Administration Site Conditions | 1249 | 1249 |
| Nervous System Disorders | 1126 | 1126 |
| Cardiac Disorders | 1001 | 1001 |
| Respiratory, Thoracic And Mediastinal Disorders | 823 | 823 |
| Investigations | 800 | 800 |
| Gastrointestinal Disorders | 772 | 772 |
| Metabolism And Nutrition Disorders | 672 | 672 |
| Renal And Urinary Disorders | 643 | 643 |
| Skin And Subcutaneous Tissue Disorders | 565 | 565 |
| Musculoskeletal And Connective Tissue Disorders | 428 | 428 |
| Infections And Infestations | 285 | 285 |
| Immune System Disorders | 261 | 261 |
| Hepatobiliary Disorders | 186 | 186 |

Number of Cases

REACTION GROUP



Search Term Amlodipine Besylate Received Year 6 of 50 Reporter Type Healthcare Profes... Age Group 2 of 8

Age group filter applied

Total number of cases based on applied filter

Cases by Sex

FDA Adverse Events Reporting System (FAERS) Public Dashboard

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 5,325

Serious Cases (including deaths) 4,952

Death Cases 1,554

Reaction Groups & Sex

| Reaction Group | Select category | Number of Cases | Male | Not Specified | Female |
|--|-----------------|-----------------|--------------|---------------|--------------|
| Total Cases | | 5,325 | 2,660 | 63 | 2,602 |
| Psychiatric Disorders | | 1,895 | 956 | 20 | 919 |
| Injury, Poisoning And Procedural Complications | | 1,882 | 894 | 8 | 980 |
| Vascular Disorders | | 1,317 | 670 | 3 | 644 |
| General Disorders And Administration Site Conditions | | 1,249 | 583 | 10 | 656 |
| Nervous System Disorders | | 1,126 | 608 | 13 | 505 |
| Cardiac Disorders | | 1,001 | 505 | 4 | 492 |
| Respiratory, Thoracic And Mediastinal Disorders | | 823 | 398 | 2 | 423 |
| Investigations | | 800 | 390 | 5 | 405 |
| Gastrointestinal Disorders | | 772 | 326 | 10 | 436 |
| Metabolism And Nutrition Disorders | | 672 | 307 | - | 365 |
| Renal And Urinary Disorders | | 643 | 362 | 1 | 280 |
| Skin And Subcutaneous Tissue Disorders | | 565 | 277 | 10 | 278 |
| Musculoskeletal And Connective Tissue Disorders | | 420 | 182 | 9 | 229 |
| Infections And Infestations | | 285 | 150 | 3 | 132 |
| Immune System Disorders | | 261 | 71 | 16 | 174 |
| Hepatobiliary Disorders | | 186 | 120 | 2 | 64 |
| Eye Disorders | | 186 | 77 | - | 109 |
| Blood And Lymphatic System Disorders | | 180 | 103 | - | 77 |
| Surgical And Medical Procedures | | 98 | 44 | - | 54 |

Reaction Groups & Sex

| Reaction Group | Female (Cases) | Male (Cases) | Not Specified (Cases) |
|--|----------------|--------------|-----------------------|
| Psychiatric Disorders | 1,895 | 1,882 | 0 |
| Injury, Poisoning And Procedural Complications | 1,882 | 1,882 | 0 |
| Vascular Disorders | 1,317 | 1,317 | 0 |
| General Disorders And Administration Site Conditions | 1,249 | 1,249 | 0 |
| Nervous System Disorders | 1,126 | 1,126 | 0 |
| Cardiac Disorders | 1,001 | 1,001 | 0 |
| Respiratory, Thoracic And Mediastinal Disorders | 823 | 823 | 0 |
| Investigations | 800 | 800 | 0 |
| Gastrointestinal Disorders | 772 | 772 | 0 |
| Metabolism And Nutrition Disorders | 672 | 672 | 0 |
| Renal And Urinary Disorders | 643 | 643 | 0 |
| Skin And Subcutaneous Tissue Disorders | 565 | 565 | 0 |
| Musculoskeletal And Connective Tissue Disorders | 420 | 420 | 0 |
| Infections And Infestations | 285 | 285 | 0 |
| Immune System Disorders | 261 | 261 | 0 |
| Hepatobiliary Disorders | 186 | 186 | 0 |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP

Age group filter applied

Additional filter capabilities for Reporter Type

Cases by Reporter Type

Total number of cases based on applied filter

The screenshot displays the FDA Adverse Events Reporting System's dashboard for the drug Amlodipine Besylate. At the top, there are several filter dropdowns: Received Year (2015), Reporter Type (Healthcare Professional, selected), and Age Group (2 of 8). Below these are buttons for 'Search Term' (Amlodipine Besylate), 'Report a Problem', 'FAQ', and a link to the 'Amlodipine Besylate' product page.

Key statistics on the dashboard include:

- Total Cases: 5,325
- Serious Cases (including deaths): 4,952
- Death Cases: 1,554

A callout points to the 'Reporter Type' dropdown, which is set to 'Healthcare Professional'. Another callout points to the 'Age Group' filter, which is set to '2 of 8'. A third callout points to the total case count of 5,325.

The main content area shows a table of reaction groups and their corresponding case counts. A bar chart to the right visualizes these counts.

| Reaction Group | Number of Cases | Healthcare Professional |
|--|-----------------|-------------------------|
| Total Cases | 5,325 | 5,325 |
| Psychiatric Disorders | 1,895 | 1,895 |
| Injury, Poisoning And Procedural Complications | 1,882 | 1,882 |
| Vascular Disorders | 1,317 | 1,317 |
| General Disorders And Administration Site Conditions | 1,249 | 1,249 |
| Nervous System Disorders | 1,126 | 1,126 |
| Cardiac Disorders | 1,001 | 1,001 |
| Respiratory, Thoracic And Mediastinal Disorders | 823 | 823 |
| Investigations | 800 | 800 |
| Gastrointestinal Disorders | 772 | 772 |
| Metabolism And Nutrition Disorders | 672 | 672 |
| Renal And Urinary Disorders | 643 | 643 |
| Skin And Subcutaneous Tissue Disorders | 565 | 565 |
| Musculoskeletal And Connective Tissue Disorders | 428 | 428 |
| Infections And Infestations | 285 | 285 |
| Immune System Disorders | 261 | 261 |
| Hepatobiliary Disorders | 186 | 186 |
| Eye Disorders | 186 | 186 |
| Blood And Lymphatic System Disorders | 180 | 180 |
| Surgical And Medical Procedures | 98 | 98 |

Reaction Groups & Reporter Type

The bar chart displays the number of cases for different reaction groups. The x-axis represents the number of cases, ranging from 0 to over 2,000. The y-axis lists the reaction groups. The bars are colored yellow, except for one grey bar representing 'Not Specified'.

| Reaction Group | Number of Cases |
|--|-----------------|
| Psychiatric Disorders | 1,895 |
| Injury, Poisoning And Procedural Complications | 1,882 |
| Vascular Disorders | 1,317 |
| General Disorders And Administration Site Conditions | 1,249 |
| Nervous System Disorders | 1,126 |
| Cardiac Disorders | 1,001 |
| Respiratory, Thoracic And Mediastinal Disorders | 823 |
| Investigations | 800 |
| Gastrointestinal Disorders | 772 |
| Metabolism And Nutrition Disorders | 672 |
| Renal And Urinary Disorders | 643 |
| Skin And Subcutaneous Tissue Disorders | 565 |
| Musculoskeletal And Connective Tissue Disorders | 428 |
| Infections And Infestations | 285 |
| Immune System Disorders | 261 |
| Hepatobiliary Disorders | 186 |
| Not Specified | 186 |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

REACTION GROUP



Age group filter applied

Total number of cases based on applied filter

Cases by Reporter Region

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 5,325

Serious Cases (including deaths) 4,952

Death Cases 1,554

Cases by Reporter Region

Reaction Groups & Reporter Region

| Reaction Group | Number of Cases | Domestic | Foreign | Not Specified |
|--|-----------------|--------------|--------------|---------------|
| Total Cases | 5,325 | 2,682 | 2,626 | 17 |
| Psychiatric Disorders | 1,895 | 1,405 | 486 | 4 |
| Injury, Poisoning And Procedural Complications | 1,882 | 1,112 | 769 | 1 |
| Vascular Disorders | 1,317 | 589 | 726 | 2 |
| General Disorders And Administration Site Conditions | 1,249 | 527 | 713 | 9 |
| Nervous System Disorders | 1,126 | 381 | 740 | 5 |
| Cardiac Disorders | 1,001 | 585 | 414 | 2 |
| Respiratory, Thoracic And Mediastinal Disorders | 823 | 359 | 460 | 4 |
| Investigations | 800 | 296 | 497 | 7 |
| Gastrointestinal Disorders | 772 | 224 | 544 | 4 |
| Metabolism And Nutrition Disorders | 672 | 299 | 372 | 1 |
| Renal And Urinary Disorders | 643 | 299 | 342 | 2 |
| Skin And Subcutaneous Tissue Disorders | 565 | 189 | 371 | 5 |
| Musculoskeletal And Connective Tissue Disorders | 420 | 130 | 287 | 3 |
| Infections And Infestations | 285 | 102 | 183 | - |
| Immune System Disorders | 261 | 205 | 56 | - |
| Hepatobiliary Disorders | 186 | 34 | 152 | - |
| Eye Disorders | 186 | 35 | 148 | 3 |
| Blood And Lymphatic System Disorders | 180 | 27 | 153 | - |
| Surgical And Medical Procedures | 98 | 47 | 49 | 2 |

Reaction Groups & Reporter Region

| Reaction Group | Domestic | Foreign | Not Specified |
|--|----------|---------|---------------|
| Psychiatric Disorders | 1,405 | 486 | 4 |
| Injury, Poisoning And Procedural Complications | 1,112 | 769 | 1 |
| Vascular Disorders | 589 | 726 | 2 |
| General Disorders And Administration Site Conditions | 527 | 713 | 9 |
| Nervous System Disorders | 381 | 740 | 5 |
| Cardiac Disorders | 585 | 414 | 2 |
| Respiratory, Thoracic And Mediastinal Disorders | 359 | 460 | 4 |
| Investigations | 296 | 497 | 7 |
| Gastrointestinal Disorders | 224 | 544 | 4 |
| Metabolism And Nutrition Disorders | 299 | 372 | 1 |
| Renal And Urinary Disorders | 299 | 342 | 2 |
| Skin And Subcutaneous Tissue Disorders | 189 | 371 | 5 |
| Musculoskeletal And Connective Tissue Disorders | 130 | 287 | 3 |
| Infections And Infestations | 102 | 183 | - |
| Immune System Disorders | 205 | 56 | - |
| Hepatobiliary Disorders | 34 | 152 | - |
| Eye Disorders | 35 | 148 | 3 |
| Blood And Lymphatic System Disorders | 27 | 153 | - |
| Surgical And Medical Procedures | 47 | 49 | 2 |

Data as of August 31, 2017

This page displays the number of cases identified for the product of interest by "Reaction Group" and the reported age of the patient. "Reaction Groups" are based on a classification of the side effect (also known as "Reaction" or adverse event or adverse drug reaction), using the MedDRA dictionary of adverse event terms. For example, "Cardiac Disorders" is one of the "Reaction Groups" defined by the MedDRA dictionary as a grouping of several related "Reactions" such as "Cardiac Arrest", and "Cyanosis". A case may contain more than one "Reaction Group". The age has been categorized based on the reported age by the patient. "Not Specified" indicates the patient's age was not reported.

QUESTIONS 9



Rebecca has extended her search and now she wants to view the information for only domestic cases and under nervous system disorders.

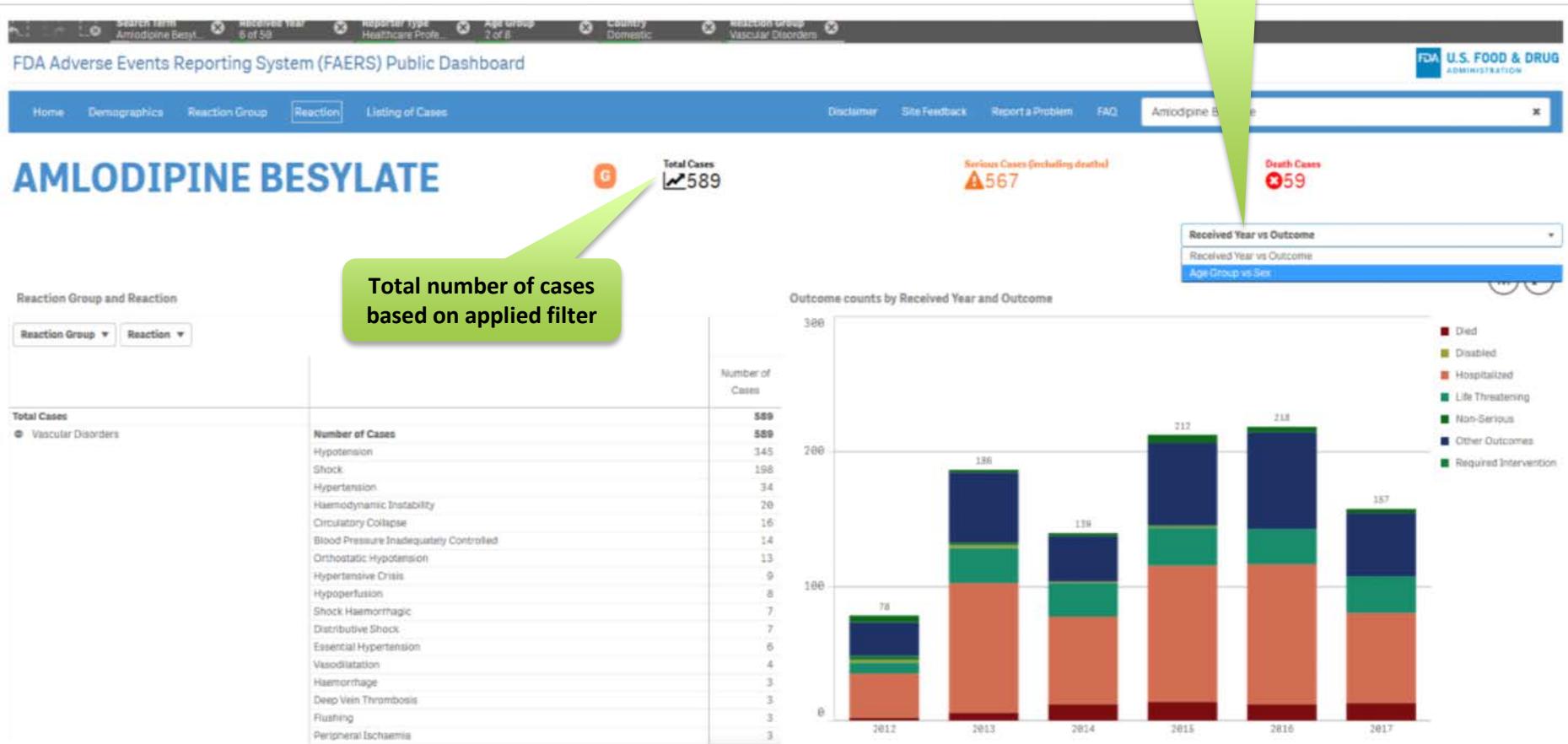
Which selections steps are the best to get quickly to results?

- a. Click on graph view and select “Nervous System Disorders” and “Domestic”
- b. Click on table view and select “Nervous System Disorders” and “Domestic”
- c. a or b

REACTION



Cases by Reaction Year vs Outcomes



REACTION



Cases by Age Group vs Sex

QUESTIONS 10



Rebecca was reviewing the chart “Reaction Year vs Outcome”. She noticed that cases have one or more outcomes. Is this correct that one case can have one or more reported outcomes?

- a. Yes
- b. No

QUESTIONS 11



Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
- d. Not enough information to determine the causal relation

QUESTIONS 11



Rebecca has found 3 cases on “Deep Vein Thrombosis” from product search “Amlodipine Besylate.” Does she has enough information to determine that “Amlodipine Besylate” cause the reaction “Deep Vein Thrombosis?” Choose the best answer.

- a. “Amlodipine Besylate” caused serious “Deep Vein Thrombosis” reaction
- b. “Amlodipine Besylate” did not cause serious “Deep Vein Thrombosis” reaction
- c. “Amlodipine Besylate” may have caused “Deep Vein Thrombosis” reaction
- d. Not enough information to determine the causal relation

One or more of these outcomes or reported reactions in a report does not necessarily mean that the suspect product of interest was the cause of the reported outcomes or reactions. Also reported narrative is not available in the public data.

LINE LISTING



Total number of cases based on applied filter

Sort Option

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Demographics Reaction Group Reaction Listing of Cases Disclaimer Site Feedback Report a Problem FAQ Amlodipine Besylate

AMLODIPINE BESYLATE

Total Cases 589

Serious Cases (including death) 567

Death Cases 59

| Case ID | Suspect Product Names | Suspect Product Active Ingredients | Reason for Use | Reactions | Serious | Outcomes | Sex | Event Date | Latest FDA Recell |
|----------|--|--|---|--|-------------|--|--------|-------------|-------------------|
| 9371793 | - | Amlodipine Besylate | Intentional Overdose | Metabolic Acidosis;Hypotension;SI... Tachycardia;Overdose;A... | Serious | Hospitalized | Female | 01-APR-2013 | 25-JUN-2013 |
| 8336357 | Viagra | Sildenafil Citrate,Amlodipine Besylate | Erectile Dysfunction;Hypertension | Drug Ineffective;Chest Pain;Wrong Technique In Product Usage | Serious | Other Outcomes | Male | 01-JAN-2011 | 17-FEB-2012 |
| 18528890 | Amiodarone | Amlodipine Besylate,Basiliximab;Tacrolimus | Hypertension;Unknown Indication;Renal Transplant | Respiratory Rate Decreased;Bilirubin Conjugated | Serious | Hospitalized;Other Outcomes | Male | 01-JUN-2014 | 28-OCT-2014 |
| 8482696 | Bystolic;Norvasc | Nebivolol Hydrochloride;Amlodipine Besylate | Cardiac Disease;Heart Rate Irregular;Hypertension;Seizure | Renal Failure;Palpitations;Abd. Distension;Oedema | Serious | Other Outcomes | Female | 01-MAY-2011 | 06-APR-2012 |
| 8515582 | Norvasc;Humira | Atalimumab;Amlodipine Besylate;Lisinopril | Gastroesophageal Reflux Disease;Product Used For Unknown Indication;Psoriatic Arthritis | Headache;Oedema;Peripheral Palpitations;Potassium | Non-Serious | Non-Serious | Female | 01-OCT-2011 | 18-MAY-2012 |
| 18212221 | Vasotec;Lyrica;Enbrel;Ampyra;Ryth... | Amlodipine Besylate;Cyclobenzaprine Hydrochloride;Efavirenz;Piperacillin Sodium;Tazobactam | Arthritis;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia | Retching;Alpecia;Impaired Mouth Ulceration;Fatigue;Colp... | Serious | Hospitalized;Other Outcomes | Female | 02-FEB-2007 | 07-JUL-2014 |
| 11538606 | Macrodantin;Cipro;Wellbutrin;Macr... | Nitrofurantoin(Nitrofurantoin Monohydrate);Lisinopril;Bupropion Hydrochloride;Ciprofloxacin | Product Used For Unknown Indication | Loss Of Consciousness;Hypotension;Urinary Drug | Serious | Other Outcomes | Female | 02-JUN-2015 | 16-OCT-2015 |
| 8256880 | Amiodarone;Herceptin | Trastuzumab;Amlodipine Besylate;Epothilone D;Metoprolol Succinate;Carbamazepine;Lorazepam | Breast Cancer;Product Used For Unknown Indication | Dehydration;Dialysis;Hypotension;Urinary Tract Infection;Drug | Serious | Hospitalized | Female | 02-SEP-2005 | 31-MAR-2012 |
| 8846567 | Lanoxin And Hydrochlorothiazide;Amlodipine;Co... | Carvedilol;Amlodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product | Hypertension;Non-Small Cell Lung Cancer | Anuria;Hypotension;A... Respiratory Distress Syndrome;Acute Kidney Injury | Serious | Died;Other Outcomes;Disable... | Male | 02-SEP-2012 | 09-APR-2014 |
| 8847273 | Coreg | Carvedilol;Clonidine;Hydrochlorothiazide;Potassium;Amlodipine Besylate | Hypertension | Sepsis;Respiratory Distress Syndrome;Acute Kidney Injury | Serious | Disabled;Other Outcomes;Died;H... Threatening | Male | 02-SEP-2012 | 05-FEB-2013 |
| 18574185 | Lioresal;Amlodipine | Amlodipine Besylate;Baclofen | Muscle Spasticity;Product Used For | Incorrect Roy... | Serious | Life | Male | 03-OCT-2014 | 18-NOV-2014 |

Case IDs

Search within each displayed column

Additional columns available to view

LINE LISTING



FDA Adverse Events Reporting System (FAERS) Public Dashboard

Total number of cases based on applied filter

Sort Option

Case IDs

Search within each displayed column

Additional columns available to view

AMLODIPINE BESYLATE

| Case ID | Suspect Product Names | Suspect Product Active Ingredients | Reason for Use | Reactions | Serious | Outcomes | Sex | Event Date | Latest FDA Recel... |
|----------|---|--|--|---|-------------|---|--------|-------------|---------------------|
| 9371793 | - | Amiodipine Besylate | Intentional Overdose | Metabolic Acidosis;Hypotension;SI-Tachycardia;Overdose,A... | Serious | Hospitalized | Female | 01-APR-2013 | 25-JUN-2013 |
| 8336357 | Vagra | Sildenafil Citrate;Amiodipine Besylate | Erectile Dysfunction;Hypertension | Drug Ineffective;Chest Pain;Wrong Technique In Product Usage | Serious | Other Outcomes | Male | 01-JAN-2011 | 17-FEB-2012 |
| 18528890 | Amiodipine | Amiodipine Besylate;Basiliximab;Tacrolimus | Hypertension;Immunosuppression;Used For Unknown Indication;Renal Transplant | Respiratory Rate Decreased;Bilirubin Conjugated | Serious | Hospitalized;Other Outcomes | Male | 01-JUN-2014 | |
| 8482696 | Bystolic;Norvasc | Nebivolol Hydrochloride;Amiodipine Besylate | Cardiac Disorders;Heart Rate Irregular;Hypertension;Seizure | Renal Failure;Palpitations;Abd. Distension;Oedema | Serious | Other Outcomes | Female | 01-MAY-2011 | |
| 8515583 | Norvasc;Humira | Adalimumab;Amiodipine Besylate;Lisinopril | Gastroesophageal Reflux Disease;Product Used For Unknown Indication;Peptic Arthritis | Headache;Oedema Peripheral;Palpitations;Potassium | Non-Serious | Non-Serious | Female | 01-OCT-2011 | |
| 19212221 | Vasotec;Lyrica;Enbrel;Ampyra;Ryth... | Amiodipine Besylate;Cyclobenzaprine Hydrochloride;Lefunomide;Piperacillin Sodium;Tazobactam | Arthritis;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia;Flatulence | Retching;Alopecia;Jugular Impaired;Mouth Ulceration;Fatigue;Colic | Serious | Hospitalized;Other Outcomes | Female | 02-FEB-2007 | |
| 11536606 | Macrodantin;Cipro;Wellbutrin;Macr... | Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Bupropion Hydrochloride;Ciprofloxacin | Product Used For Unknown Indication | Loss Of Consciousness;Hypotension | Serious | Other Outcomes | Female | 02-JUN-2015 | |
| 8256800 | Amiodipine;Herceptin | Tрастузумаб;Amiodipine Besylate;Eptololone D;Metoprolol Succinate;Carboplatin;Lorazepam | Breast Cancer;Product Used For Unknown Indication | Dehydration;Diarrhoea | Serious | Hospitalized | Female | 02-SEP-2005 | 31-JUL-2012 |
| 6846567 | Lisinopril Hydrochlorothiazide;Amiodipine;Co... | Carvedilol;Amiodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product | Hypertension;Non-Small Cell Lung Cancer | Anaemia;Hypotension;A... Respiratory distress Syndrome;Kidney... | Serious | Died;Other Outcomes;Disable... | Male | 02-SEP-2012 | 06-SEP-2014 |
| 8847273 | Coreg | Carvedilol;Clonidine;Hydrochlorothiazide;Potassium;Amiodipine Besylate | Hypertension | Sepsis;Admission;Respiratory Distress Syndrome;Hypotension | Serious | Disabled;Other Outcomes;Died;H... Threatening | Male | 02-SEP-2012 | 15-FEB-2013 |
| 18574105 | Lioresal;Amiodipine | Amiodipine Besylate;Baclofen | Muscle Spasticity;Product Used For... | Incorrect Route | Serious | Life | Male | 03-OCT-2014 | 18-NOV-2014 |

LINE LISTING



Search within each displayed column

FDA Adverse Events Reporting System (FAERS) Public Dashboard

FDA U.S. FOOD & DRUG ADMINISTRATION

AMLODIPINE BESYLATE

Total Cases **589**

Serious Cases (including deaths) **567**

Death Cases **59**

| Case ID | Suspect Product Names | Suspect Product Active Ingredients | Reason for Use | Actions | Serious | Outcomes | Sex | Event Date | Latest FDA Recel... | |
|----------|---|--|---|---|---|-----------------------------|---|-----------------------------|---------------------|-------------|
| 9371793 | - | Amlodipine Besylate | Intentional Overdose | X ✓ | Serious | Hospitalized | Female | 01-APR-2013 | 25-JUN-2013 | |
| 8336357 | Viagra | Sildenafil Citrate;Amlodipine Besylate | Erectile Dysfunction | X ✓ | Chest Pain;Serious | Other Outcomes | Male | 01-JAN-2011 | 17-FEB-2012 | |
| 18528890 | Amlodipine | Amlodipine Besylate;Basiliximab;Tacrolimus | Hypertension;Used For Unsuccessful Transplant | X ✓ | Adenocarcinoma Of Colon;Hypertension | Hospitalized;Other Outcomes | Male | 01-JUN-2014 | 29-OCT-2014 | |
| 8492696 | Bystolic;Norvasc | Nitivoltol Hydrochloride;Amlodipine Besylate | Cardiac Disease;Irregular Heartbeat | X ✓ | Angina Pectoris;Anticoagulant Therapy | Other Outcomes | Female | 01-MAY-2011 | 06-APR-2012 | |
| 8515582 | Norvasc;Humira | Adalimumab;Amlodipine Besylate;Lisinopril | Gastroesophageal Reflux Disease;Product Indication;Poor Response | X ✓ | Angina Pectoris;Coronary Artery Disease | Non-Serious | Female | 01-OCT-2011 | 18-MAY-2012 | |
| 10212221 | Valetac;Lyrica;Entrel;Amyoya;Rhyth... | Amlodipine Besylate;Cyclobenzaprine Hydrochloride;Leflunomide;Piperacillin Sodium;Tazobactam | Arthritis;Atrial Fibrillation;Blood Pressure Measurement;Fibromyalgia;Fluid | X ✓ | Antiretroviral Therapy;Product Used For | Severe;Judged | Serious | Hospitalized;Other Outcomes | 02-FEB-2007 | 07-JUL-2014 |
| 11538666 | Macrodantin;Cipro;Wellbutrin;Macr... | Nitrofurantoin;Nitrofurantoin Monohydrate;Lisinopril;Supropion Hydrochloride;Corofloxacin | Product Used For Unknown Indication | X ✓ | Loss Of Consciousness;Hypotension;Pruritic;Drug | Other Outcomes | Female | 02-JUN-2015 | 16-OCT-2015 | |
| 8256880 | Amlodipine;Herceptin | Trastuzumab;Amlodipine Besylate;Epothilone D;Metoprolol Succinate;Carboxipran;Lorazepam | Breast Cancer;Product Used For Unknown Indication | X ✓ | Vision Blurred;Dehydration;Disorientation | Serious | Hospitalized | Female | 02-SEP-2005 | 31-MAY-2012 |
| 8846567 | Losartan And Hydrochlorothiazide;Amlodipine;Co... | Carvedilol;Amlodipine Besylate;Clonidine;Hydrochlorothiazide;Potassium;Investigational Product | Hypertension;Non-Small Cell Lung Cancer | X ✓ | Anaemia;Hypotension;Acute Respiratory Distress Syndrome;Acute Kidney Injury | Serious | Died;Other Outcomes;Disable... | Male | 02-SEP-2012 | 04-SEP-2014 |
| 8847373 | Coreg | Carvedilol;Clonidine;Hydrochlorothiazide;Potassium;Amlodipine Besylate | Hypertension | X ✓ | Sepsis;Acute Respiratory Distress Syndrome;Hypoxia;Hypotension | Serious | Disabled;Other Outcomes;Died;Highly Threatening | Male | 02-SEP-2012 | 15-FEB-2013 |
| 18574105 | Lioresal;Amlodipine | Amlodipine Besylate;Baclofen | Muscle Spasticity;Product Used For | X ✓ | Incorrect Route Of Drug | Serious | Life | Male | 03-OCT-2014 | 18-NOV-2014 |

Data as of August 31, 2013

QUESTIONS 12



Rebecca got results of 589 total cases for “Amlodipine Besylate.” She finds the line listing is very useful and is curious to see all available data columns.

Is it possible to view all the columns at one time?

- a. Yes
- b. No

QUESTIONS 12



Rebecca got results of 589 cases for “Amlodipine Besylate” based on the filter applied. She finds the line listing is very useful and curious to see all available data columns. Is it possible to view all column at one time?

- a. Yes
- b. No

The export option is not yet available to view all data columns. The only way is to select from the column library to include in the screen to view.

QUESTIONS 13

Rebecca wants detailed narratives to perform further analysis on these reports. The narrative data column is not available to public. What is the best method to get to the full details of all ICSRs?

- a. Make a FOIA request with all 589 case
- b. Send a Request to DrugInfo@FDA.HHS.GOV
- c. Send a Request to FDA Helpdesk
- d. None of the above

CONCLUSION



- FAERS dashboard gives the public and industry a more user friendly platform for accessing FAERS reports
- FAERS dashboard makes adverse event data more accessible and transparent.
- Existence of a report does not establish causation
- Rates of occurrence cannot be established with reports

